

PRINCE EDWARD ISLAND
PHARMACY BOARD

#7-20424 Trans Canada Highway, South Shore Professional Building
P.O. Box 89, Crapaud, P.E.I. COA IJO
Phone: (902) 658-2780 Fax: (902) 658-2198 E-mail: peipharm@pei.aibn.com

Member Organization of the National Association of Pharmacy Regulatory Authorities (NAPRA)

Narcotic and Controlled Drug Reconciliation Guidelines 2011

Introduction

The public expects that pharmacists will take reasonable steps to protect drugs on their premises from loss, theft or diversion. This expectation is reflected in federal and provincial legislation including the Narcotic Control regulations, the Food and Drug Regulations, and the PEI Pharmacy Act and Regulations. This expectation extends to both the pharmacy manager and the pharmacist on duty.

Fulfilling this expectation requires diligence against both external and internal (i.e. pharmacy staff) loss, theft and diversion (LT&D). Suitable locks and alarms, and diligence in identifying and addressing fraudulent prescriptions are examples of activities to protect against external LT&D. Protecting the drugs from internal LT&D requires additional strategies including a hiring and screening process for staff, and robust narcotic and controlled drug reconciliation procedures.

Reconciliation is a careful and methodical process of auditing the recorded versus actual purchases, dispensed, and on-hand quantities of drugs. While they are not quickly performed activities, they are important for identifying problems which can subsequently be investigated and addressed.

Purpose

The Narcotic and Controlled Drug Reconciliation policy is intended to provide pharmacy managers with an effective means to assist them in assuring that the narcotic and controlled drugs in the pharmacy are secure from internal loss, theft and diversion. It represents the minimum requirements expected of pharmacies in achieving this purpose.

Policy

Pharmacy managers will ensure the following reconciliations are performed for narcotic and controlled drugs:

1.0 Physical inventory reconciled with Computer or Manual Perpetual Inventory

A physical count of the inventory provides an essential baseline for future reconciliations.

- i. A physical count of the inventory of the drugs should be done on a monthly basis
- ii. In addition to routine monthly counts, a physical count of the inventory will be taken whenever there is a change in pharmacy manager, after any break and enter of theft from the pharmacy, after any recent change in pharmacy staff, or in any event that creates concern that security of the drugs may have been compromised.
- iii. The inventory should not be solely counted by the same individual who exclusively enters the purchases in the computer or manual purchase log*.

- iv. The inventory should be documented in a separate and dedicated record that is retained for two years. The record will include:
 - The name, strength, form and quantity of the drug counted
 - The signature of the counter
 - The date the count was taken
- v. The inventory reconciliation record must be stored in a readily retrievable format in the pharmacy, in a location separate and distant from the storage of the monitored drugs.
- vi. The Physical count of the inventory must be reconciled with the perpetual inventory count (i.e. inventory in computer or on manual perpetual inventory record*).
- vii. Any discrepancy must be investigated by reviewing records of purchases and sales. Identified source of discrepancy and reconciling entries must be recorded on the inventory reconciliation record.

Shortages which cannot be reconciled must be reported to the Office of Controlled Substances (OCS) at health Canada within 10 days (the OCS "*Loss or theft Report form for controlled Substances and Precursors*" can be accessed on the PEIPB website http://napra.ca/Content_Files/Files/PEI/HC_Loss_Theft_Report_Form09.pdf

- viii. A copy of the report sent to the OCS must be forwarded to the PEIPB.

2.0 Invoices reconciled with Purchase Record

Invoices for purchases of monitored drugs should be randomly audited to ensure they are accurately entered into the computer record or manual perpetual inventory record*.

- i. Pharmacies must establish a feasible process to achieve this reconciliation in consideration of the capabilities and limitations of the pharmacy's software system (i.e. audit performed in real-time [same day as the product is received] or retrospectively).
- ii. Pharmacies should audit a random selection of 10% of narcotic and controlled drug invoices received each month.
- iii. The date and time of the audit must not be predictable.
- iv. Any discrepancy is to be investigated, addressed and documented.
- v. A record of invoices and/or purchases that have been found not to be recorded is to be maintained and filed with the inventory reconciliation record.

3.0 Sales Report reconciled with Filed Prescriptions

The Narcotic and Controlled Drug Sales Report should be printed and reviewed monthly, reconciling it with the filed prescriptions for narcotic and controlled drugs dispensed to ensure that

- A valid prescription is on file for the dispensing of the monitored drug
 - All prescriptions are accounted for (i.e. there are no missing prescription numbers in the prescription file)
- i. Pharmacies should review a random selection of 10% of narcotic and controlled drug prescriptions filled each month. The review will include obtaining the original written prescription and reconciling it with the computer record of the dispensing.
 - ii. Any discrepancy is to be investigated, addressed and documented.
 - iii. A record of identified discrepancies and their resolution will be maintained and filed with the inventory record.

4.0 Reconciliation of Purchases and Sales Records

It is necessary to ensure that all monitored narcotic and controlled drugs can be accounted for through the dispensing of valid prescriptions.

Pharmacies will print a report of any manual adjustments to the computer inventory each month and document the reason(s) for these adjustments(s).

In the absence of being able to generate a report of any manual adjustments to the computer inventory, a pharmacy will routinely reconcile the purchases of each narcotic or controlled drug with its sales.

- i. Each month, a pharmacy will audit a random selection of 10% of the narcotic and controlled drug inventory, reconciling the total purchases with the calculated [(sales + on-hand quantity) – beginning inventory]
- ii. Any discrepancy must be investigated by reviewing records of purchases and sales. Identified source of discrepancy and reconciling entries must be recorded on inventory record.
- iii. Any shortage which cannot be reconciled must be reported to the Office of Controlled Substances (OCS) at health Canada within 10 days (form can be accessed on the PPEIPB website http://napra.ca/Content_Files/Files/PEI/HC_Loss_Theft_Report_Form09.pdf)
- iv. A copy of the report sent to the OCS must be forwarded to the PEIPB.

Note

* If a pharmacy does not have a computer generated perpetual inventory, then it must maintain a manual perpetual inventory. This includes keeping a separate record for each drug on which is recorded each purchase and each sale with a resulting running balance.

Responsibility

It is the responsibility of the pharmacy manager, pharmacy owner, and every director of a corporation that owns a pharmacy to ensure compliance with this policy.

Physical Count of Inventory reconciled with Computer/Manual Record

Date: _____

A computer generated inventory report can be used as the documenting form for the reconciliation, recording on that report the actual physical count for each drug and an explanation for any variation / difference. The report is to be signed by the individual taking the inventory and the pharmacy manager.

Drug (Name, Strength, form)	Computer/ Manual Perpetual Record of on-hand inventory	Actual Count of On-hand inventory	Difference	Explanation for Difference

Signature of Counter: _____

Signature of PhC Manager: _____

